



Food and Drug Administration
Rockville MD 20857

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September 17, 2001

Carl David D'Ruiz, MPH
Ciba Specialty Chemicals Corporation
4090 Premier Drive
P.O. Box 2444
High Point, NC 27261-2444

Dear Dr. D'Ruiz:

Your petition requesting the Food and Drug Administration to re-open the administrative record to allow for the submission and evaluation of additional safety data supporting the Category I safety and long-term use status of triclosan in the proposed 21 CFR Part 333, the OTC Tentative Final Monograph for Health-Care Antiseptic Drug Products, was received by this office on 09/17/01. It was assigned docket number 75N-183H/CP 9 and it was filed on 09/17/01. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,


Gloria Ortega
Dockets Management Branch

75N-183H

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